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IN THE UNITED STATES DISTRICT COURT
THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC., Plaintiffs and Counterclaim Defendants, v. HANMI USA, INC., HANMI PHARMACEUTICAL CO., LTD., HANMI FINE CHEMICAL CO., LTD, and HANMI HOLDINGS CO., LTD., Defendants and Counterclaim Plaintiffs.	Civil Action No. 3:11-CV-00760-JAP-TJB

DEFENDANTS' BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION TO AMEND THEIR DISCLOSURE OF ASSERTED CLAIMS OF U.S. PATENT NO. 5,714,504

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Defendants Hanmi USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd. and Hanmi Holdings Co., Ltd. (collectively "Hanmi") respectfully submit this brief in opposition to the motion of Plaintiffs AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, KBI Inc. and KBI-E Inc. (collectively "AstraZeneca") to add newly asserted claims of U.S. Patent 5,714,504 ("the '504 patent") (Ex. 1).[1]

I. INTRODUCTION

This is a Hatch-Waxman patent infringement case. The Local Patent Rules of this District use a carefully crafted framework in such cases, according to which the patent holder first makes a Disclosure of Asserted Claims that lists each claim of each patent that is allegedly infringed, followed by an accused party's disclosure of contentions in opposition to the patent holder's assertions of infringement. This approach not only is logical from a legal standpoint, but fair from a case management standpoint. The patentee's asserted claims control the scope of the infringement case, and the accused infringer's non-infringement and invalidity contentions necessarily are responsive to the asserted claims, not vice versa.

Moreover, which of its claims are allegedly infringed is controlled by the patent holder's assessments of its own patents and the accused products, nothing else. Contrary to AstraZeneca's suggestion, the Local Patent Rules do not call for a disclosure of claims selected by patentee to initially test out for survival of an accused party's legal theories and contentions, and indeed there is no provision permitting select disclosure and secret reservation of assertable claims to assert in the event selected claims do not survive. Such piecemeal prosecution of a case is fundamentally at odds with the letter and intent of the Rules. AstraZeneca first had a

[1] All exhibits referenced herein are attached to the Declaration of Renita S. Rathinam submitted herewith.

description of Hanmi's accused esomeprazole strontium product in December, 2010 upon receipt of the Paragraph IV Notice Letter, and then received a copy of Hanmi's full NDA describing the product in detail in early April, 2011, as part of Hanmi's early disclosures. No new facts about Hanmi's product came to light prior to AstraZeneca's decision to assert claims 1, 2, 4 and 6-7 of the '504 patent on May 11, 2011.

The Local Patent Rules properly mandate that leave to amend contentions requires the moving party to demonstrate that, proceeding diligently, it could not reasonably have made the additional disclosure by the established deadline.

Here, no new underlying operative facts have arisen with respect to infringement by the accused Hanmi products since well before this case was filed. On the contrary, AstraZeneca's extensive legal team of outside and in-house counsel have been litigating the Nexium® patent portfolio for six years and have known the active ingredient in the accused Hanmi products to be esomeprazole strontium since the receipt of Hanmi's Notice of Paragraph IV Certification (the "Notice Letter") (Ex. 2) in December of 2010. Of the eleven Orange Book listed patents that were the subject of Hanmi's Paragraph IV notification letter of December 29, 2010, AstraZeneca's team made a calculated decision to sue only on the '504 and '192 patents. Given the clear requirements of the Rules, claims 1, 2, 4 and 6-7 are the only claims of the '504 patent that AstraZeneca's vast legal team concluded would be infringed by Hanmi's accused products, if approved by the FDA. This is not a case of new facts coming to light. Because AstraZeneca initially determined that claims 3, 5 and 10 of the '504 patent would not be infringed by Hanmi's proposed esomeprazole strontium salt with respect to the newly proposed claims covering different salts, it simply cannot meet its burden of showing the diligence required for leave to expand its assertions at this stage of the litigation.

If AstraZeneca were permitted to back off from its initial conclusion that claims 3, 5 and 10 were not infringed by Hanmi's proposed product, and add new infringement claims in the present circumstances, every patentee could do it in every case, end-running the very purpose of the Local Patent Rules and essentially eviscerating them. A patentee then could dribble out new patents or claims one or two at a time, and seek to delay each case indefinitely. Such a circumstance not only would flout the beneficial framework of the Local Patent Rules, but would prejudice the rights of drug manufacturers seeking to provide their medicines to the public as provided by the terms of the Hatch-Waxman Act.

Moreover AstraZeneca's assertion that Hanmi's May 25, 2011 "expanded array of defenses" somehow necessitated its belated attempt to add claims to the case is disingenuous. AstraZeneca boldly misrepresents that Hanmi advised of the invalidity of claims 1, 2, 4 and 6-7 of the '504 patent for the first time in its May 25, 2011 non-infringement and invalidity contentions. To the contrary, as shown below, AstraZeneca has been aware of Hanmi's position that the asserted claims of '504 are invalid if construed to encompass any salt other than Na^+, Mg^{2+}, Li^+, Ca^{2+}, K^+ or $N^+(R)_4$ salts of esomeprazole (viz., strontium salt product) since Hanmi's Notice Letter of December 29, 2010, let alone since the Answer and Counterclaims (ECF No. 7) filed in this case which challenged the validity of each and every claim of the '504 patent.

AstraZeneca's motion is baseless and improper and should be denied. AstraZeneca's initial determination that claims 3, 5 and 10 were not infringed – with full knowledge of Hanmi's proposed product – stands as a stark admission of non-infringement of those claims. A party's change of substantive positions, especially when not well-grounded in fact, as here, does not meet the good cause or diligence standards of the Local Patent Rules.

II. STATEMENT OF FACTS

Hanmi is the holder of New Drug Application ("NDA") No. 202342[2] seeking approval to market esomeprazole *strontium* capsules in the United States. AstraZeneca's approved product is Nexium®, which contains esomeprazole *magnesium.* Therefore, because the products contain different salt forms, Hanmi was required to submit a Section 505(b)(2) (21 U.S.C. § 355(b)(2)) application to the FDA, meaning that although Hanmi's submission relies on safety and efficacy information from the reference listed drug, Hanmi's product is not identical to AstraZeneca's product. As part of its NDA, Hanmi submitted a Paragraph IV certification against each of AstraZeneca's eleven listed Orange Book patents for Nexium®, including U.S. Patent No. 5,714,504 ("the '504 patent") and U.S. Patent No. 5,877,192 ("the '192 patent") (collectively "the patents-in-suit") that AstraZeneca now asserts against Hanmi.

On December 29, 2010, as required by 21 U.S.C. § 355(b)(3)(D)(ii) and 21 C.F.R. § 314.52, Hanmi sent AstraZeneca a Notice of Paragraph IV Certification (the "Notice Letter") (Ex. 2). The Notice Letter included a 38 page (single spaced) detailed statement of the legal and factual bases, including issues concerning non-infringement and invalidity, for Hanmi's Paragraph IV certifications. The Notice Letter further "reserve[d] the right to assert other non-infringement, invalidity, and/or unenforceability positions at a later time, and to alter the positions stated herein based on information that is presently unknown to Hamni." *Id.* at Exhibit A, page 2 (HAN0026235). Of course, in any Hatch-Waxman case, the defendants'

[2] AstraZeneca incorrectly characterizes Hanmi's NDA 202343 as an ANDA seeking to market a generic version of Nexium® (magnesium esomeprazole). (*See* Plaintiffs' Memorandum in Support of Their Motion to Amend Their Disclosure of Asserted Claims ("Plaintiffs' Mem.") ECF No. 82 at 1). Hanmi's NDA is directed to an original strontium salt formulation of esomeprazole, for which Hanmi has been issued its own patent.

ultimate contentions evolve over the litigation from the initial Paragraph IV positions, as discovery into the asserted claims progresses.

With respect to the '504 patent, Hanmi asserted that none of claims 1-7 and 10 was infringed because, *inter alia*, due to claim construction or the literal language of those claims, none of them covered an esomeprazole strontium product, either literally or under the doctrine of equivalents.[3] *Id*. at pages 27-31 (HAN0026263- 6267).

Claims 3, 5 and 10 recited specific salt forms of esomeprazole other than strontium (Ex. 1), and were initially determined by AstraZeneca not to be infringed (ECF No. 60) based on the Notice Letter and Hanmi's production of its NDA in early April, 2011. (Ex. 3, Defendant's April 1, 2011 Letter Producing NDA 202342 (HAN0000001-HAN0022677); see also Ex. 4, Hanmi's Initial Non-infringement and Invalidity Contentions Pursuant to L. Pat. R. 3.6 at page 1 (again specifying that HAN0000001 - HAN0022677 corresponds to NDA 202342)).

AstraZeneca's present motion is based wholly on the allegation that it had no prior knowledge that Hanmi ever previously advised AstraZeneca specifically of its position that claims 1, 2, 4 and 6-7, directed to an "alkaline salt" of esomeprazole, if construed to encompass any salt other than Na^+, Mg^{2+}, Li^+, Ca^{2+}, K^+ or $N^+(R)_4$ salts of esomeprazole, would be invalid under 35 U.S.C. § 112, first paragraph. But AstraZeneca is wrong. Indeed, Hanmi's Notice Letter made clear that:

> Furthermore, if the claim term "pure solid state alkaline salt of the (-)-enantiomer of [omeprazole]" were not limited to the six specific salts disclosed in the '504 patent, the patent would be invalid for lack of enablement. *See Generation II Orthotics, Inc. v. Med. Tech., Inc.,*

[3] Claims 8 and 9 of the '504 patent do not purport to claim salt forms of esomeprazole, and are not relevant to this case.

> 263 F.3d 1356, 1365 (Fed. Cir. 2001)… As explained above above, claims 1-7 and 10 of the '504 patent require "a pure solid state alkaline salt of the (-)-enantiomer of [omeprazole]." However, salt selection is inherently unpredictable. *See Sanofi-Synthelabo v. Apotex, Inc.,* 492 F. Supp. 2d 353, 374 (S.D.N.Y. 2007)… Accordingly, if the Court were to construe the claim term "pure solid state alkaline salt of the (-)-enantiomer of [omeprazole]" as being broader than the teachings of the '504 patent, the patent would be rendered invalid as failing to enable the full scope of claimed subject matter. And, it is well-settled that "claims are generally construed so as to sustain their validity, if possible." *Whittaker Corp. v. UNR Indus., Inc.,* 911 F.2d 709, 712 (Fed. Cir. 1990).

(Ex. 2, Notice Letter, Exhibit A at pages 28-29). Additionally, with its Notice Letter, Hanmi offered AstraZeneca confidential access to its NDA and DMF (Ex. 2 at Exhibit B), and produced its NDA and DMF to AstraZeneca's counsel in the course of this litigation on April 1, 2011 (Ex. 3) – long before AstraZeneca advised that claims 1, 2, 4 and 6-7 were allegedly infringed on May 18, 2011.

Over the last six years, AstraZeneca has filed at least seven separate complaints to block the introduction of other manufacturers' introductions of generic esomeprazole products relating to the patents-in-suit in this District alone. Continuing in its efforts to enforce its esomeprazole patents, AstraZeneca commenced this action against Hanmi on February 9, 2011 (ECF No. 1) seeking to block the introduction of Hanmi's esomeprazole strontium capsules in the United States before the expiration of the patents-in-suit.

Hanmi answered the complaint and asserted counterclaims on March 1, 2011 (ECF No. 7). Hanmi asserted that each claim of the '504 patent was not infringed and was invalid.

On April 1, 2011, Hanmi served its complete NDA, which fully described the products at issue (Ex. 3).

On May 11, 2011, the Court issued a Letter Order setting the schedule for the case (ECF No. 56). AstraZeneca was given even more time than the default times set under the Local patent Rules to serve its Disclosure of Asserted Claims.

Pursuant to the Letter Order, on May 18, 2011, AstraZeneca served its Disclosure of Asserted Claims pursuant to Local Patent Rule 3.1. With respect to the '504 patent, AstraZeneca asserted infringement of claims 1, 2, 4 and 6-7, all reciting a "pure solid state alkaline salt" of esomeprazole. Claims 3 and 10 that AstraZeneca now seeks to add recite six specific species of alkaline salts -- Na^+, Mg^{2+}, Li^+, Ca^{2+}, K^+ or $N^+(R)_4$ -- of esomeprazole, while claim 5 is limited to the Mg^{2+}, salt (Ex. 1).

Since being sued on the '504 and '192 patents in February, Hanmi has invested significant resources and time evaluating them, preparing for discovery, claim construction, and developing its defenses and counterclaims. AstraZenenca's May 18, 2011 determination that only the "alkaline salt" claims of the '504 patent would allegedly be infringed by Hanmi's esomeprazole strontium product focused the analysis leading to Hanmi's detailed preliminary contentions served May 25, 2011 (Ex. 4, Initial Non-infringement and Invalidity Contentions Pursuant to Local Patent Rule 3.6(c)), as well as its First Request for Production of Documents and Things on July 20, 2011.

Relying on AstraZeneca's determination that claims 3, 5 and 10 were not infringed, Hanmi has invested significant resources and time in strategically selecting terms for construction, invested significant resources and time in proposing claim constructions, and determining relevant supporting intrinsic and extrinsic as to asserted claims 1, 2, 4 and 6-7. The parties have now already exchanged terms for construction on August 1, 2011 and

preliminary constructions and supporting evidence pursuant to Local Patent Rule 4.2 on August 15, 2011.

Notably, AstraZeneca first raised the issue of asserting new claims on July 1, 2011 (Ex. 5, Email chain re AstraZeneca's request to add claims 3, 5, and 10 at July 1, 2011 - Tracy to Rathinam)), and Hanmi advised that it would oppose on July 5th, following the holiday weekend (*Id.* at July 5, 2011 Rathinam to Tracy). Over a month later and after Hanmi's continued substantial investments in developing its case based on assertion of alkaline salt claims, through the instant motion AstraZeneca belatedly seeks to amend its May 18, 2011 infringement contentions to add new claims of the '504 patent.

III. ARGUMENT

A. Legal Standard

Local Patent Rule 3.6(b) provides that the party asserting patent infringement shall serve a "Disclosure of Asserted Claims" listing each claim of each patent allegedly infringed by the defendant. In Hatch-Waxman actions, this early disclosure of each patent and claim allegedly infringed is particularly important to "help narrow the focus of a generic's invalidity contentions" and "eliminates speculation and added work by the generics in formulating their non-infringement and invalidity contentions." Report of the District of New Jersey Local Rules Committee, Explanatory Notes for 2011 Amendments. Thus, "[t]he rules are designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed." *THF Publications, Inc. v. Doskocil Mfg. Co., Inc.*, 705 F. Supp. 2d 361, 365-66 (D.N.J. 2010) (quoting *Atmel Corp. v. Info. Storage Devices, Inc.*, 1998 U.S. Dist. LEXIS 17564 (N.D. Cal. Nov. 5, 1998)); *see also Berger v. Rossignol Ski Co., Inc.*, 2006 U.S. Dist. LEXIS 23085, *7 (N.D. Cal. April 25, 2006) ("The patent rules are

designed to avoid "vexatious shuffling of positions" that could occur if the parties are permitted to freely modify their infringement contentions at any point in the action.") (quoting *JSR Corp. v. Tokyo Ohka Kogyo Co.*, 2001 U.S. Dist. LEXIS 24959, *18 (N.D. Cal. Sep. 13, 2001)).[4]

In contrast to the liberal standards for amending pleadings, Local Patent Rule 3.7 permits amendment of disclosures "only by order of the Court upon a timely application and showing of good cause." Local Patent Rule 3.7; *THF Publications*, 705 F. Supp. 2d 361, 365-66. "Good cause" requires that the party seeking to amend its contentions show diligence. *O2 Micro Int'l Ltd. v. Monolithic Power Systems, Inc.*, 467 F.3d 1355, 1366 (Fed. Cir. 2006) (addressing N.D. Cal. Local Patent Rule 3-7). The burden is on the party seeking leave to amend to demonstrate diligence, not on the opposing party to demonstrate a lack of diligence. *Id.* And that burden requires that the movant show that it could not reasonably have made the additional disclosure by the established deadline. *Softvault Sys., Inc v. Microsoft Corp.*, 2007 U.S. Dist. LEXIS 33060, *3 (E.D. Tex. 2007).

B. AstraZeneca Does Not Have Good Cause To Add To Its Disclosure Of Asserted Claims

AstraZeneca attempts to manufacture "new" information in this case based on Hanmi's May 25, 2011 invalidity contentions. However, Hanmi's legal theories of invalidity of claims 1, 2, 4 and 6-7 have nothing to do with AstraZeneca's determination of which its claims are allegedly infringed. A patent holder's decision to assert claims is controlled by its assessment of an accused product and its own patents, not by opposing counsel's work product. Per the

[4] Because this district and the Eastern District of Texas adopted verbatim the Local Patent Rules of the Northern District of California, the Court may look to those cases for guidance. *THF Publications*, 705 F. Supp. 2d at 365 n.3.

definition of "Disclosure of Asserted Claims" and the Court's Scheduling Order (ECF No. 56), it was incumbent upon AstraZeneca to disclose on May 18, 2011 each of the claims allegedly infringed by the accused products. AstraZeneca's evaluations found that claims 3, 5 and 10 were not infringed – obviously because Hanmi's proposed product contained a different salt form than claimed. As a hedge against the possibility that an independent claim might be held invalid, every plaintiff has every incentive to assert every allegedly infringed dependent claim. The fact that AstraZenenca deliberately chose not to assert claims 3, 5 and 10 simply means it concluded that it could not, in good faith, pursue infringement of claims directed to wholly different compounds.

AstraZeneca's tactic appears designed to "pocket" certain claims, then "dole them out" piecemeal in contravention of the Rules. The motive appears to be simple delay, but the merits are futile. Such a scheme is wholly contrary to both the Local Patent Rules and long-standing fundamental rules of Federal Rules of Civil Procedure, such as Rules 16 and 11 which require diligence and a good faith basis for assertion. The fact that AstraZeneca's several law firms and numerous in-house counsel initially concluded that claims 3, 5 and 10 of the '504 patent were not infringed, completely undermines any current allegations of diligence in proposing the futile amendment.

Except for AstraZeneca's late realization that its originally asserted claims are not infringed and invalid, there is nothing new here. Since Hanmi's December 29, 2010 Notice Letter and April production of its NDA, nothing has changed. The accused products have not changed and no new facts about them have been revealed in discovery. Hanmi has always taken the position that the claims of the asserted patents are not infringed, and are invalid if construed more broadly than the scope enabled by the teachings of the '504 patent. (*See* Ex. 2,

Notice Letter, Exhibit A at 27-31; ECF No. 7). The fact that Hanmi further developed its contentions between the time of the Notice Letter and its preliminary contentions is of no moment. AstraZeneca cannot meet its required burden to show the necessary diligence required under the Local Patent Rules for amending its infringement contentions.

Local Patent Rule 3.7 identifies a number of "examples of circumstances that may, absent undue prejudice to the adverse party, support a finding of good cause" for amending contentions, including: (a) an unfavorable claim construction; (b) recent discovery of material prior art despite earlier diligence; (c) recent discovery of nonpublic information about the accused product not previously discovered despite diligent efforts; (d) disclosure of an infringement contention by a Hatch-Waxman Act party asserting infringement under L. Pat. R. 3.6(g) that requires response because it was not previously presented or reasonably anticipated; and (e) consent by the parties and a showing that the amendment will not delay the case. None of these situations apply here.

AstraZeneca does not and cannot urge any of the listed grounds, or anything akin to them, for belatedly asserting new claims.[5] Rather, all AstraZeneca can offer in support of the diligence required to meet its burden of showing good cause is that Hanmi's May 25, 2011 invalidity contentions contained expanded allegations and defenses – that AstraZeneca

[5] AstraZeneca apparently attempts to equate its present situation with Local Patent Rule 3.7 good cause example (d), "disclosure of an infringement contention by a Hatch-Waxman Act party asserting infringement under L. Pat. R. 3.6(g) that requires response by the adverse party because it was not previously presented or reasonably anticipated." (*See* Plaintiffs' Mem. at 2-3.) While the Local Patent Rule 3.7 examples are not exhaustive, the drafters easily could have included such an example based on invalidity contentions, but did not. That omission is entirely logical and proper because the scope of invalidity contentions properly is driven by the infringement contentions of the patent holder, not the other way around. In any case, AstraZeneca had clear notice of the bases of invalidity of the asserted claims, as pointed out above.

supposedly could not have foreseen – not disclosed in Hanmi's December 29, 2010 Notice Letter or March 1, 2011 answer and counterclaims. (Plaintiffs' Mem. at 1-2.) Thus, AstraZeneca argues that it could not identify all of the claims that it should assert because it did not know all of Hanmi's grounds for invalidity of the patents-in-suit. (Plaintiffs' Mem. at 3), and having now recognized that its asserted claims are not infringed and/or invalid, improperly seeks to add new claims.

Hanmi's March 1, 2011 Answer and Counterclaims (ECF No. 7), however, includes the allegation that all claims of the '504 patent are invalid under 35 U.S.C. § 112 (ECF No. 7 (Second Separate Defense; Second Count – Declaration of Invalidity of the '504 Patent)). As AstraZeneca of course well knows, 35 U.S.C. § 112 specifically includes indefiniteness and lack of written description as a grounds for invalidity. Thus, AstraZeneca was on notice for well over two months before disclosing its asserted claims that indefiniteness and lack of written description were in play as defenses to all claims of the '504 patent. And, as discussed above, nonenablement was specifically raised in the December, 2010 Notice Letter (Ex. 2, at Exhibit A, pages 28-29). Nevertheless, AstraZeneca evaluated infringement, and elected not to assert claims 3, 5 and 10.

Moreover, AstraZeneca's suggestion that the scope of the defenses dictates the scope of the claims asserted legally is inconceivable. Essentially, AstraZeneca argues that, because Hanmi challenged the validity of claim 1 in its invalidity contentions, AstraZeneca now is required to assert claims 3, 5 and 10 against Hanmi in case claim 1 ultimately is held invalid. That proposition, however, is true in every patent litigation, regardless of what invalidity defenses are raised in the contentions or how extensive they are. It is well-established that the validity of dependent claims survives any holding of invalidity of the claim on which they are

based, and any suggestion here that AstraZeneca's decision to assert dependent claims 3, 5 and 10 somehow depended on the scope of Hanmi's challenges to claim 1 is contrary to law.

In short, Hanmi properly pled the invalidity of all claims of the '504 patent in its answer and counterclaims, including based on § 112 lack of written description. AstraZeneca made a calculated decision not to assert claims 3, 5 and 10 in its May 18, 2011 contentions, even though it had Hanmi's December 29, 2010 Notice Letter (invalidity based on § 112 lack of enablement), March 1, 2011 Answer and Counterclaims (invalidity of each claim) and full NDA describing the accused product in hand. *See Softvault*, 2007 U.S. Dist. LEXIS at *4-5 (denying motion to amend infringement contentions when amendment not based on "new information" and patent holder – "either by choice or through lack of diligence" – did not assert earlier priority date). AstraZeneca has shown no diligence, either with respect to its initial contentions or its bringing of the instant motion two and a half months after Hanmi's May 25, 2011 non-infringement and invalidity contentions. *See O2 Micro*, 467 F.3d at 1367 (affirming denial of leave to amend infringement contentions when patent holder waited almost three months to move to amend from when it had reason to know of infringement theory).[6]

On top of its lack of diligence, AstraZeneca's attempt to interject new claims into the case at this juncture threatens to disrupt the carefully crafted framework the Local Patent Rules envision for Hatch-Waxman cases. In particular, the local rules plainly call for the patentee's

[6] The circumstances in the present case are in sharp contrast to the circumstances in the cases cited by AstraZeneca in which amendment was permitted. In *THF Publications*, for example, the Local Patent Rule disclosures were "in their infancy," discovery demands had not yet been exchanged and the content of the parties' future *Markman* briefing would not be altered. 705 F. Supp. 2d at 363-64, 366. In *Mediostream, Inc. v. Microsoft Corp.*, 2010 U.S. Dist. LEXIS 110420, *13 (E.D. Tex. October 18, 2010), the patent holder did not have the necessary information in time for its contentions due to delays of the defendant in providing discovery.

disclosure of asserted claims – not an accused party's invalidity contentions – to set the stage for the parties' legal positions. *See* Report of the District of New Jersey Local Rules Committee, Explanatory Notes for 2011 Amendments (the early disclosure of each patent and claim allegedly infringed is designed to "help narrow the focus of a generic's invalidity contentions" and "eliminates speculation and added work by the generics in formulating their non-infringement and invalidity contentions"). Permitting AstraZeneca to amend its contentions now, with no showing of diligence, will contravene these proper principles of Hatch-Waxman case management embodied in the Local Patent Rules and result in the "vexatious shuffling of positions" that the Rules specifically were designed to avoid. *See Berger*, 2006 U.S. Dist. LEXIS 23085 at *7 (quoting *JSR Corp.*, 2001 U.S. Dist. LEXIS at *18).

C. Hanmi Would Be Unfairly Prejudiced By AstraZeneca's Proposed Addition of Asserted Claims

AstraZeneca argues that Hanmi will not be prejudiced by the addition of new claims in this case because "the claim construction process is just starting, and nothing beyond claim construction has yet been scheduled." (Plaintiffs' Mem. at 2; *see* Plaintiffs' Mem. at 4.) Despite AstraZeneca's arguments, however, permitting the amendment would result in real prejudice to Hanmi for a number of reasons.

Hamni would be prejudiced if the Court were to grant AstraZeneca's motion for leave to amend because Hamni has relied on AstraZeneca's infringement contentions for over three months and, based on those contentions, incurred substantial cost in assessing the issues concerning the claims asserted against it and developing its case strategy tailored to the specific claims asserted against it. *See Berger*, 2006 U.S. Dist. LEXIS 23085 at *12. Hanmi's invalidity and non-infringement contentions are based on plaintiffs' calculated determination

and disclosure of allegedly infringed claims. AstraZeneca has admitted that claims 3, 5 and 10 of the '504 patent would not be infringed by Hanmi's proposed NDA products.

Should AstraZeneca's motion be granted over this opposition, Hanmi agrees with AstraZeneca that existing case schedule need not be extended. Nonetheless, should AstraZeneca ever urge to the contrary, Hanmi will be prejudiced by any delay the case schedule would have on the timing of the ultimate resolution of this litigation. Unlike other previous Nexium® patent challengers who have either settled with AstraZeneca and have obtained an agreed market entry date[7], or those who are not "first applicants" under 21 U.S.C. §355(j)(5)(B)(iv)(II)(bb)[8], the 30-month stay of Hanmi's 505(b)(2) application expires in mid-2013 and FDA is free to finally approve Hanmi's application at that time. Any delays in the present case schedule would unfairly postpone the finality of the Court's decision on the merits of Hanmi's challenges, and unfairly increase the legal uncertainty and thus the risk of any prospective product launch after FDA approval.

Although this is a relatively new case, AstraZeneca's present motion is yet another in a line of tactics to delay the orderly progression of this matter, to Hanmi's prejudice. Notably, after Hanmi filed its Answer and Counterclaims (ECF No. 7, March 1, 2011), AstraZeneca filed a frivolous Motion to Strike certain of Hanmi's Defenses and Counterclaims as, *e.g.,* improperly plead, and as not providing "fair notice" to AstraZeneca as to its claims and

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[7] *See e.g.,* Ranbaxy Pharmceuticals (*Astrazeneca AB et al v. Ranbaxy Pharmaceuticals, Inc. et al,* 3:05-cv-05553-JAP -TJB (D.N.J.)); Teva and Ivax (*Astrazeneca AB et al v. Ivax Corporation et al,* 3:06-cv-01057-JAP-TJB (D.N.J.)); Dr. Reddy's (*Astrazeneca AB el al v. Dr. Reddy's Laboratories, Ltd. et al,* 3:08-cv-00328-JAP-TJB (D.N.J.)).

[8] Hanmi believes that, *e.g.* Sun Pharmaceuticals (*Astrazeneca AB et al v. Sun Pharma Global FZE et al,* 3:10-cv-1017-JAP-TJB (D.N.J.)) may not be such a "first applicant" under the statute.

defenses.[9] (ECF No. 16, March 24, 2011). When Hanmi later proposed a schedule to the Court that would align the present Markman Schedule with the schedule in other pending cases (ECF No. 51, 5/3/2011; ECF No. 52, 5/3/2011), AstraZeneca opposed that request, stating that its Motion to Strike was "dispositive", because:

> The Court's ruling on this motion will impact the scope of submissions required by the Local Patent Rules. As one example, under the Local Patent Rules, AstraZeneca would be required to disclose its asserted claims this Thursday (May 12); however, *AstraZeneca should not be required to make such decisions until it knows the scope of the claims, defenses, and counterclaims properly raised by Hanmi, which depends on how the Court rules on AstraZeneca's motion.*

(ECF No. 55, 5/10/11) (emphasis added). After adding new counsel to the case, AstraZeneca voluntarily withdrew its motion to strike in exchange for Hanmi's agreement to a modest extension of three dates (ECF No. 74, 7/19/11) that would not otherwise impact the Court-ordered schedule in this case. Without a doubt, AstraZeneca's present motion seeks the very same relief as its withdrawn motion to strike -- the ability to "disclose its asserted claims" only *after* it "knows the scope of the claims, defenses, and counterclaims properly raised by Hanmi." Having withdrawn its motion seeking that relief, representing to the Court its reasons for so doing (ECF No. 55, 5/10/11), AztraZeneca should not now be permitted to avoid its previous representations to the court and seek to delay the schedule further.

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[9] AstraZeneca's motion was frivolous because it raised the identical arguments on at least three prior occasions, *and lost all three times*. *See, e.g., Astra Aktiebolag v. Andrx Pharm., Inc.*, No. 98-6521, 1998 U.S. Dist. LEXIS 22787, at *5 (S.D. Fla. Nov. 2, 1998) ("Defendant has met the liberal pleading requirements of the Federal Rules of Civil Procedure"); *Astra Aktiebolag v. Cheminor Drugs, Ltd.*, No. 99-8927, 2000 U.S. Dist. LEXIS 2540, at *5 (S.D.N.Y. Mar. 8, 2000) ("Astra is not prejudiced by the inclusion of additional defenses and counterclaims"); *Astra Aktiebolag v. Kremers Urban Develop.*, No. 99-8928, 2000 U.S. Dist. LEXIS 2511 (S.D.N.Y. Mar. 8, 2000) (same). In each of those earlier cases, AstraZeneca moved to strike certain defenses and dismiss invalidity counterclaims, arguing that it had been denied "fair notice" by the defendant's insufficient pleadings. *See e.g.,* D.I. 27, p. 1.

Hanmi will also be forced to incur significant additional expense associated with AstraZeneca's re-do of its asserted claims. Hanmi has not undertaken the same analyses it would have otherwise undertaken had claims 3, 5 and 10, directed to six specific species of alkaline salts (Na^+, Mg^{2+}, Li^+, Ca^{2+}, K^+, $N^+(R)_4$) of esomeprazole, been previously asserted. Various analyses were not crafted with an eye toward the interplay of genus/species claims and scope analysis in view of the multiple patents procured by AstraZeneca year after year on one or more of these very same species. Hanmi would essentially be required to re-tailor its defenses and counterclaims as developed to date, amend its preliminary contentions, and go through rounds of additional contentions by both parties for these new claims while it should be focusing on the core issues presented to date. *See Softvault*, 2007 U.S. Dist. LEXIS 33060 at *5-6.

Hanmi has played by the rules and no new facts have come to light. Simple fairness requires that AstraZeneca also play by the rules and abide by its disclosures in accord with the Court's protocol for disclosure of contentions.

D. AstraZeneca's Proposed Amendment is Futile

AstraZeneca argues that it would be "substantially prejudiced" if the instant motion is denied and it is not permitted to add the new claims to this case in the event that the asserted claims are held invalid. (Plaintiffs' Mem. at 2, 3-4.) Putting aside of the lack of diligence in timely selecting the claims to assert, AstraZeneca is not prejudiced because adding the proposed additional claims to this case would be futile.

An assertion of these claims is indeed frivolous, as AstraZeneca initially determined by choosing not to assert them with full knowledge of every detail of Hanmi's product. As discussed above, claims 3, 5 and 10 that AstraZeneca now seeks to add are directed to one of

six specific alkaline salts -- Na^+, Mg^{2+}, Li^+, Ca^{2+}, K^+ and $N^+(R)_4$ -- of esomeprazole. The specific salts covered by these claims simply do not include a strontium (Sr) salt, and therefore cannot be literally infringed. AstraZeneca properly understood these claims not to cover the accused Hanmi's strontium salt product under the doctrine of equivalents.[10] Claims 3, 5 and 10 simply cannot be expanded under the doctrine of equivalents to include a strontium formulation, resulting in entire vitiation of the species recitations of the these claims. *See Planet Bingo LLC v. GameTech Int'l, Inc.*, 472 F.3d 1338, 1344 (Fed. Cir. 2006); *Sage Products, Inc. v. Devon Ind., Inc.,* 126 F.3d 1420, 1429 (Fed. Cir. 1997) (the doctrine of equivalents may not be used to erase meaningful structural and functional limitations of a claim).

IV. CONCLUSION

For the reasons stated above, Hanmi respectfully request that the Court deny Plaintiffs' Motion to Amend Their Disclosure of Asserted Claims.

Dated: August 22, 2011

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[10] If the Court is inclined to grant AstraZeneca's motion, Hanmi respectfully notes its intent to seek discovery as to why these claims were not previously asserted and whether or not there is any reasonable basis to assert these claims, including discovery of any allegedly privileged materials that would appear to contradict the present AstraZeneca position. It is believed that AstraZeneca would possess various documents and opinions concluding no infringement, which should become discoverable in the context of an about-face, belated assertion of infringement. Hanmi also reserves the right to seek its fees in connection having to defend against belated and frivolously asserted claims.

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CERTIFICATE OF SERVICE

I hereby certify that on August 22, 2011, I caused a copy of the foregoing **DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO AMEND THEIR DISCLOSURE OF ASSERTED CLAIMS, EXHIBITS 1- 5** and **DECLARATION OF RENITA S. RATHINAM** to be served upon the following counsel through the Court's ECF system and via email.

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